PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	10 NOV 2008
Applicant's or agent's file reference 782-P08-047	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2008/074941	29 August 2008	30 August 2007

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A 61 B 17/56(2008.04)
USPC - 606/62, 28, 60

Applicant
MARCTEC, LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	28 October 2008	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-40	YES
	Claims	None	NO
Inventive step (IS)	Claims	8-12, 28-32	YES
	Claims	1-7, 13-27, 33-40	NO
Industrial applicability (IA)	Claims	1-40	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-7, 13-27, and 33-40 lack an inventive step under PCT Article 33(3) as being obvious over Aeschlimann et al., hereinafter Aeschlimann in further view of Haeg et al., hereinafter Haeg.

Referring to claim 1, Aeschlimann discloses a method for stabilizing a body tissue or bone (abstract), comprising the steps of: inserting an elongate fastener, having a proximal fastener end and a distal fastener end through body tissue to contact the bone or tissue with the distal fastener end (para [0010]); firmly contacting the proximal fastener end with a vibratory horn, the horn connected to a source of vibratory energy, the horn operative to transfer vibratory energy to the fastener (, Figure 1, number 6 and 7, para [0012]), wherein contact between the horn and the proximal fastener end is sufficiently firm to prevent generation of sufficient heat to substantially soften the proximal fastener end as a result of vibration between the proximal fastener end and the horn (Figure 1, para [0012]), and wherein vibratory energy is transmitted through the fastener to cause vibration at the distal end of the fastener sufficient to produce heat between the distal fastener end (para [0012]) and the tissue or bone (para [0012]-[0013]), the produced heat sufficient to soften the heat softenable material coated on the fastener (para [0010]), thereby bonding the fastener to the tissue or bone after vibratory energy is discontinued and the heat softenable material cools and hardens (para [0012]-[0013]); wherein a connection is thus formed between the body tissue through which the elongated fastener is passed and the fastener, thereby stabilizing the bone or tissue. Aeschlimann does not explicitly disclose the step wherein a fastener is bonded to a coated object already fixated to the body tissue or bone. However, Haeg discloses a method of stabilizing components in an implantable device (abstract), wherein one component of the device is coated with heat softenable material and is fixated to another part of the device through vibratory energy, thus stabilizing components of the device (col 5, ln 20-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to take the method of stabilizing a body tissue or bone using an implant fixated to the tissue or bone as taught by Aeschlimann with the method of fixating multiple components of an implant using vibratory energy as taught by Haeg to arrive at the claimed invention, through routine experimentation, for the purpose of providing greater strength and stability to the traumatized tissue or bone.

Referring to claim 2, Aeschlimann as modified by Haeg discloses the method of claim 1, wherein the vibratory energy is ultrasonic vibratory energy (abstract).

Referring to claim 3, Aeschlimann as modified by Haeg discloses the method of claim 1 wherein the heat softenable coating of the coated object is selected from the group consisting of: thermoplastic, acrylic, acrylics polycarbonate, styrene, polyethylene, polyether ether ketone, poly propylene, polylactic acid (PLA), polyglycolic acid (PGA), copolymers ofPGA and PLA (para [0011]).

Referring to claim 4, Aeschlimann as modified by Haeg discloses the method of claim 1, wherein the amount of heat required to soften the softenable material is substantially confinable, due to the thermal properties of the coating and the fastener, to an area of contact between the coated object and the distal fastener end, thereby protecting living body tissue near the contact between the distal fastener end and the coated object from substantial thermal tissue necrosis (para [0012]-[0013]).

Referring to claim 5, Aeschlimann as modified by Haeg discloses the method of claim 1, wherein at least a portion of the distal fastener end includes heat softenable material, and wherein the heat softenable material of the distal fastener end softens during transmission of vibratory energy (para [0012]-[0013]).

Referring to claim 6, Aeschlimann as modified by Haeg discloses the method of claim 5. Neither Aeschlimann nor Haeg explicitily disclose wherein the softenable material of the distal fastener end is the same material as the object coating, and wherein the softenable material of the distal fastener end and the coating mix when softened, thereby welding the distal fastener to the object. However, both Aeschlimann and Haeg disclose using thermoplastics in their respective inventions (see abstracts). Additionally, it would have been obvious to one of ordinary skill at the time of the invention, absent unexpected results, to use the same heat softenable material on the fastener and coated on the object already fastened to the bone or tissue so as to have uniformity during liquidification and re-hardening of the materials.

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Supplemental Box

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Box V

Referring to claim 7, Neither Aeschlimann nor Haeg explicitly disclose a method of repairing a loosened implant, the implant secured within the body by a binding material that will soften and flow when heated and that has formed one or more gaps between the implant and body tissue, comprising the steps of: contacting binding material proximate one or more gaps with a vibratory horn; applying vibratory energy to the vibratory horn using a source of vibratory energy, the vibratory horn thereby vibrating against and heating binding material proximate the vibratory horn, until the binding material has softened and flows to cross one or more gaps to form a bridge between the implant and body, thereby closing one or more gaps; and, discontinuing vibratory energy and allowing the binding material to cool; whereby closing one or more gaps serves to reduce the loosening of the implant. However, it would have been obvious to one of ordinary skill at the time of the invention to arrive at the above disclosed method of repairing a loosened implant having the above references before him. As discussed above Aeschlimann as modified by Haeg teach a method of securing an object to a bone or tissue and then securing or fastening another object such as a screw or pin to the first anchored object using heat softenable material and vibratory energy. Furthermore, Aeschlimann discloses a method of securing a plate to a tissue and then fastening an implant to said plate to avoid loosening of the plate using the same method (para [0061]). Therefore, one of ordinary skill, through routine experimentation would arrive at this method for the purpose of providing greater strength and stability to a broken, loose or weak implant.

Referring to claim 13, Aeschlimann as modified by Haeg discloses the method of claim 7, wherein the binding material is bone cement (para [0011]).

Referring to claim 14, Aeschlimann as modified by Haeg discloses the method of claim 7, wherein the vibratory horn includes heat softenable material at a point of contact with the binding material proximate a gap, and further including the step of: softening heat softenable material of the vibratory horn during the step of applying vibratory energy, whereupon the heat softenable material flows into one or more gaps (para [0010]).

Referring to claim 15, Aeschlimann as modified by Haeg discloses the method of claim 14. Neither Aeschlimann nor Haeg explicitily disclose wherein the heat softenable material of the vibratory horn is the same material as the binding material. However, both Aeschlimann and Haeg disclose using thermoplastics in their respective inventions (see abstracts). Additionally, it would have been obvious to one of ordinary skill at the time of the invention, absent unexpected results, to use the same heat softenable material on the vibratory horn and binding material so as to have uniformity during liquidification and re-hardening of the materials.

Referring to claim 16, Aeschlimann discloses a method of fastening one object within the body in a therapeutic surgical procedure (para [0010]), comprising the steps of: passing a first end of a fastener to extend through a gap in each of one or more objects the fastener having a base and at least one end, the first end including heat softenable material (Figure 1, numbers 6 and 7, para [0012]); contacting the first end with a vibratory horn (para [0012]-[0013]); applying vibratory energy to the vibratory horn, operative to cause the vibratory horn to vibrate against the first end, producing heat within the first end, causing the first end to soften and expand, wherein the first end expands to a size larger than a gap in at least the object closest to the end of the first end (para [0012]-[0013]); whereby the objects through which the first end extends are secured upon the fastener, and thereby secured within the body. Aeschlimann does not explicitly disclose fastening more than one object, including affixing the base of the fastener within the body. However, Haeg discloses a method of stabilizing components in an implantable device (abstract), wherein one component of the device is coated with heat softenable material and is fixated to another part of the device through vibratory energy, thus stabilizing components of the device (col 5, ln 20-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to take the method of stabilizing a body tissue or bone using an implant fixated to the tissue or bone as taught by Aeschlimann with the method of fixating multiple components of an implant using vibratory energy as taught by Haeg to arrive at the claimed invention, through routine experimentation, for the purpose of providing greater strength and stability to the traumatized tissue or bone through fixating multiple components of a device or fastener to the bone or tissue.

Referring to claim 17, Aeschlimann as modified by Haeg discloses the method of claim 16, whereby the first end includes a heat softenable material selected from the group consisting of: thermoplastic, acrylic, acrylics polycarbonate, styrene, polyethylene, polyether ether ketone, poly propylene, polylactic acid (PLA), polyglycolic acid (PGA), copolymers ofPGA and PLA (para [0011]).

Referring to claim 18, Aeschlimann as modified by Haeg discloses the method of claim 16, wherein the fastener base is secured within the body using vibratory energy (para [0013]).

Referring to claim 19, Aeschlimann as modified by Haeg discloses the method of claim 16. Neither Aeschlimann nor Haeg explicitly disclose wherein the vibratory horn has a curved shape, and wherein the first end is caused to form a complementary curved shape upon application of vibratory energy. However, Haeg discloses wherein the volume and depth of the heat softenable material is dependent on the shape and surface are of the horn (col 10, lns 54-58). Therefore, it would have been obvious to one of ordinary skill at the time of the invention to arrive at the above disclosed shape of the vibratory horn, through routine experimentation, having the above references before him for the purpose of obtaining specific volume and/or depth of heat softenable material depending on the specific need and application thereof.

Referring to claim 20, Aeschlimann as modified by Haeg discloses the method of claim 16, wherein the vibratory energy is ultrasonic energy (abstract).

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Referring to claim 21, Aeschlimann discloses a system for stabilizing a body tissue or bone (abstract), the object to be implanted coated over at least a portion of its exterior surface with a heat softenable material (abstract), comprising: an elongate fastener, having a proximal fastener end and a distal fastener end, insertable through body tissue to contact the coated object with the distal fastener end (para [0010]); a source of vibratory energy (para [0012]-[0013]); a vibratory horn, connected to the source of vibratory energy, firmly contactable with the proximal fastener end, and operative to transfer vibratory energy to the fastener (para [0012]-[0013]), wherein contact between the horn and the proximal fastener end is sufficiently firm to prevent generation of sufficient heat to substantially soften the proximal fastener end as a result of vibration between the proximal fastener end and the horn (para [0013]), and wherein vibratory energy is transmitted through the fastener to cause vibration at the distal end of the fastener sufficient to produce heat between the distal fastener end and the coated object (para [0012]-[0013]), the produced heat sufficient to soften the heat softenable material of the coated object, thereby bonding the coated fastener to the bone or tissue after vibratory energy is discontinued and the heat softenable material cools and hardens (para [0012]-[0013]); wherein a connection is thus formed between the body tissue through which the elongated fastener is passed and the fastener, thereby stabilizing the bone or tissue. Aeschlimann does not explicitly disclose the system wherein a fastener is bonded to a coated object already fixated to the body tissue or bone. However, Haeg discloses a method of stabilizing components in an implantable device (abstract), wherein one component of the device is coated with heat softenable material and is fixated to another part of the device through vibratory energy, thus stabilizing components of the device (col 5, ln 20-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to take the system of stabilizing a body tissue or bone using an implant fixated to the tissue or bone as taught by Aeschlimann with the system of fixating multiple components of an implant using vibratory energy as taught by Haeg to arrive at the claimed invention, through routine experimentation, for the purpose of providing greater strength and stability to the traumatized tissue or bone.

Referring to claim 22, Aeschlimann as modified by Haeg discloses the system of claim 21, wherein the vibratory energy is ultrasonic vibratory energy (abstract).

Referring to claim 23, Aeschlimann as modified by Haeg discloses the system of claim 21 wherein the heat softenable coating of the coated object is selected from the group consisting of: thermoplastic, acrylic, acrylics polycarbonate, styrene, polyethylene, polyether ether ketone, poly propylene, polylactic acid (PLA), polyglycolic acid (PGA),
copolymers ofPGA and PLA (para [0011]).

Referring to claim 24, Aeschlimann as modified by Haeg discloses the system of claim 21, wherein the amount of heat required to soften the softenable material is substantially confinable, due to the thermal properties of the coating and the fastener, to an area of contact between the coated object and the distal fastener end, thereby protecting living body tissue near the contact between the distal fastener end and the coated object from substantial thermal tissue necrosis (para [0012]-[0013]).

Referring to claim 25, Aeschlimann as modified by Haeg discloses the system of claim 21, wherein at least a portion of the distal fastener end includes heat softenable material, and wherein the heat softenable material of the distal fastener end softens during transmission of vibratory energy (para [0012]-[0013]).

Referring to claim 26, Aeschlimann as modified by Haeg discloses the method of system of claim 25. Neither Aeschlimann nor Haeg explicitily disclose wherein the softenable material of the distal fastener end is the same material as the object coating, and wherein the softenable material of the distal fastener end and the coating mix when softened, thereby welding the distal fastener to the object. However, both Aeschlimann and Haeg disclose using thermoplastics in their respective inventions (see abstracts). Additionally, it would have been obvious to one of ordinary skill at the time of the invention, absent unexpected results, to use the same heat softenable material on the fastener and coated on the object already fastened to the bone or tissue so as to have uniformity during liquidification and re-hardening of the materials.

Referring to claim 27, Neither Aeschlimann nor Haeg explicitly disclose a system for repairing a loosened implant, the implant secured within the body by a binding material that will soften and flow when heated and that has formed one or more gaps between the implant and body tissue, comprising: a source of vibratory energy a vibratory horn operative to contact binding material proximate one or more gaps, the vibratory horn connected to the source of vibratory energy, and further operative upon application of vibratory energy by the source of vibratory energy to vibrate against and heat the binding material proximate the vibratory horn, until the binding material has softened and flows to cross one or more gaps to form a bridge between the implant and the body, thereby closing one or more gaps; and, wherein after the source of vibratory energy is discontinued, the binding material is allowed to cool, whereby one or more gaps are closed, serving to reduce the loosening of the implant. However, it would have been obvious to one of ordinary skill at the time of the invention to arrive at the above disclosed system of repairing a loosened implant having the above references before him. As discussed above Aeschlimann as modified by Haeg teach a method of securing an object to a bone or tissue and then securing or fastening another object such as a screw or pin to the first anchored object using heat softenable material and vibratory energy (See application of references in claim 1 above). Furthermore, Aeschlimann discloses a method of securing a plate to a tissue and then fastening an implant to said plate to avoid loosening of the plate using the same method (para [0061]). Therefore, one of ordinary skill, through routine experimentation would arrive at this system for the purpose of providing greater strength and stability to a broken, loose or weak implant.

Referring to claim 33, Aeschlimann as modified by Haeg discloses the system of claim 27, wherein the binding material is bone cement (para [0011]).

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Referring to claim 34, Aeschlimann as modified by Haeg discloses the system of claim 27, wherein the vibratory horn includes heat softenable material at a point of contact with the binding material proximate a gap, wherein the heat softenable material of the vibratory horn is softened during application of vibratory energy, whereupon the heat softenable material flows into one or more gaps (para [0010]).

Referring to claim 35, Aeschlimann as modified by Haeg discloses the system of claim 34. Neither Aeschlimann nor Haeg explicitily disclose wherein the heat softenable material of the vibratory horn is the same material as the binding material. However, both Aeschlimann and Haeg disclose using thermoplastics in their respective inventions (see abstracts). Additionally, it would have been obvious to one of ordinary skill at the time of the invention, absent unexpected results, to use the same heat softenable material on the vibratory horn and binding material so as to have uniformity during liquidification and re-hardening of the materials.

Referring to claim 36, Aeschlimann disclose a system for fastening one object within the body, comprising: a fastener having at least one end, a first end of the at least one ends extendable through a gap in each of one or more objects to be fastened, including heat softenable material operative to expand when heated (Figure 1, numbers 6 and 7, para [0012]), (para [0010]), corresponding to an implant); a source of vibratory energy (para [0012]); a vibratory horn contactable with the first end, connected to the source of vibratory energy (Figure 1, para [0012]) wherein when the source of vibratory energy is energized, the vibratory horn is operative to produce heat within the first end, causing the first end to soften and expand (para [0012]-[0013]); wherein the first end expands to a size larger than a gap in at least the object closest to the end of the first end; whereby the objects through which the first end extends are secured upon the fastener, and thereby secured within the body (para [0013]). Aeschlimann does not explicitly disclose fastening more than one object, including a base affixable in the body. However, Haeg discloses a method of stabilizing components in an implantable device (abstract), wherein one component of the device is coated with heat softenable material and is fixated to another part of the device through vibratory energy, thus stabilizing components of the device (col 5, ln 20-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to take the system of stabilizing a body tissue or bone using an implant fixated to the tissue or bone as taught by Aeschlimann with the system of fixating multiple components of an implant using vibratory energy as taught by Haeg to arrive at the claimed invention, through routine experimentation, for the purpose of providing greater strength and stability to the traumatized tissue or bone through fixating multiple components of a device or fastener to the bone or tissue.

Referring to claim 37, Aeschlimann as modified by Haeg discloses the system of claim 36, whereby the first end includes a heat softenable material selected from the group consisting of: thermoplastic, acrylic, acrylics polycarbonate, styrene, polyethylene, polyether ether ketone, poly propylene, polylactic acid (PLA), polyglycolic acid (PGA), copolymers ofPGA and PLA (para [0011]).

Referring to claim 38, Aeschlimann as modified by Haeg discloses the system of claim 36, wherein the fastener base is secured within the body using vibratory energy (para [0013]).

Referring to claim 39, Aeschlimann as modified by Haeg discloses the system of claim 36. Neither Aeschlimann nor Haeg explicitly disclose wherein the vibratory horn has a curved shape, and wherein the first end is caused to form a complementary curved shape upon application of vibratory energy. However, Haeg discloses wherein the volume and depth of the heat softenable material is dependent on the shape and surface are of the horn (col 10, lns 54-58). Therefore, it would have been obvious to one of ordinary skill at the time of the invention to arrive at the above disclosed shape of the vibratory horn, through routine experimentation, having the above references before him for the purpose of obtaining specific volume and/or depth of heat softenable material depending on the specific need and application thereof.

Referring to claim 40, Aeschlimann as modified by Haeg discloses the system of claim 36, wherein the vibratory energy is ultrasonic energy (abstract).

Claims 8-12 and 28-32 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method or system for repairing a loosened implant wherein the vibratory horn is releasably connectable to the source of vibratory energy, and is released from the source of vibratory energy after vibratory energy has been discontinued; wherein the vibratory horn is left within the body, bound to the cooled binding material.

Claims 1-40 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.